NSK

K 113717

5. 510(k) SUMMARY

MAR 0 5 2013

Submitter:	Nakanishi, Inc. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666
Contact Person:	Mr. Toshihiko Shinozaki Assistant Manager, R&D Dept. Pharmaceutical Affairs Gr. TEL: 0289(64)3380 FAX: 0289(62)6665 t-shinozaki@nsk-nakanishi.co.jp
Date Prepared:	March 5, 2013
Trade Name:	Varios 370 / Varios 370 Lux
Common Name:	Ultrasonic Scaler
Classification Name:	ELC 872.4850 Scaler, Ultrasonic
Predicate Device:	K031421 – Nakanishi Varios 350 / Varios 350 Lux
Device Description:	The Varios 370 is a compact, portable control unit powered by the iPiezo® engine. The product comes with a wide range of tip inserts, which can be attached at the distal end of the Varios 2 Handpiece transducer and vibrates at ultrasonic frequencies of 28 to 32 KHz. The Varios 370 LUX features twin LED lights, assuring generally clearer vision and easier identification of the treatment area.
Statement of Intended Use:	This product is intended only for dental clinic /dental office use. This device generates ultrasonic waves intended for use in dental applications such as scaling, root canal treatment, periodontal and cavity preparation.
Summary of Technological Characteristics:	The Varios 370 is a compact, portable control unit, allowing easy installation into any dental unit, and powered by the iPiezo® engine. During the mode of operation, a sinusoidal electrical signal, at ultrasonic frequency (f > 20Khz), is generated and delivered to the 'piezoelectric ceramic' located inside the handpiece transducer. The electrical signal is converted into mechanical vibrations and propagated to the distal end of the handpiece.
Summary of Testing:	As required by 21 CFR 820.30(g), the Varios 370 has been successfully subjected to design validation, including software validation. Software validation documentation was provided in compliance with FDA document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. In addition, the Varios 370 has been successfully tested in accordance with the following applicable standards for medical devices: • Electrical Safety: IEC 60601-1 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance) • Electrical Safety: UL 60601-1 (Medical Electrical Equipment – Part 1: General Requirements for Safety)

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- Electromagnetic Compatibility: IEC 60601-1-2 (General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests)
- Biocompatibility: ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing)
- Dentistry: ISO 22374 (Dental handpieces – Electrical-powered scalers and scaler tips)
- Sterilization: AAMI/ANSI/ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices)

Conclusion: Nakanishi, Inc. considers the Varios 370 Ultrasonic Scaler to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in primary intended use, principles of operation, design rationale, test results, and performance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2013

Nakanishi, Incorporated
C/O Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
RICHARDSON TX 75080

Re: K113717
Trade/Device Name: Varios 370 / Varios 370 Lux
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

INDICATIONS FOR USE

510(k) Number: K113717

Device Name: Varios 370 / Varios 370 Lux

Indications for Use:

This product is intended only for dental clinic /dental office use. This device generates ultrasonic waves intended for use in dental applications such as scaling, root canal treatment, periodontal and cavity preparation.

Prescription Use ____X____ (21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113717